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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/993,312	HOOD ET AL.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-77* is/are pending in the application.

4a) Of the above claim(s) *34 and 44-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-33, 35-43,75-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 11/9/07, are acknowledged. Amended claims 1, 16, 32, cancelled claim 3, and new claims 75-77 are acknowledged. Claims 34 and 44-74 remain withdrawn as being drawn to non-elected subject matter.

Applicant's arguments, filed 11/9/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-2, 4-33, 35-43, and 75-77 are herein under examination.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-33, 35-43, and 75-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Rine et al. (P/N 5,777,888). This rejection is maintained for claims 1-2, 4-33, 35-43 and necessitated by amendment for claims 75-77.

Rine et al. disclose analyzing stimulus-response patterns of a living thing using deduction protocols applied through artificial intelligence systems such as expert systems and neural networks (abstract, Figure 5) as well as computer protocol to predict myocardial infarction (col. 1, second paragraph) which represents predicting the behavior of a biochemical system, as stated in instant claims 1, 16, 32, and 75-77. Rine et al. disclose performing comparisons to deduce the mechanism of action and characteristics of the responsible stimulus (col. 5, lines 37-49) which represents a prediction of cell behavior (of a biochemical system) indicative of a changing condition, as stated in claims 1, 16, 32, and 75-77. Rine et al. disclose constructing a stimulated physical matrix (data integration map which is a physical interaction map), detecting a physical signal (value) at each unit of the physical matrix and storing the output signal matrix data with X and Y coordinates of the corresponding physical matrix unit and stimulus (i.e. value sets), and repeating this procedure including constructing a stimulated physical matrix for a plurality of stimuli to form a database (col. 2, lines 4-15) and comparing the output signal matrix to an output signal matrix database (other matrices) which represents producing and comparing two or more data integration maps obtained under different conditions. Rine et al. disclose using various conditions/perturbations, including pharmaceutical agent stimuli, suspected pathogenic agents, and radiative energy (col. 3, lines 48-51) which represent two or more different perturbed conditions, as stated instant claims 1, 7, 16, 22, 32, 36, and 75-77. The term "network" is broadly defined in several ways in the instant specification (page 10, line 26 to page 11, line 32) that includes a group of interacting molecules in two or more pathways and have common function in a biochemical function. A "network" is also defined as containing one or more components involved in a biochemical function which could be interpreted to be a cell, nucleic

acid, or countless other cellular component parts. Thus, two cells involved in each microarray as discussed by Rine et al. would qualify as two independent networks, as stated in instant claims 1, 2, 16, 17, 32, 33, and 75-77. Rine et al. disclose using a microtiter plate with 96 wells with a cell or colony of cells in each well (col. 10, lines 38-41) which represent at least 96 networks, as stated in instant claims 6, 21, and 35. Rine et al. disclose comparing an output signal matrix to an output signal matrix database (containing other matrices) for correlating candidate stimuli and responses (abstract and col. 1, line 66 to col. 2, line 3 and col. 2, lines 25-29) which represents identifying correlative changes relative to one or more of the value sets between two or more data integration maps and predicting a behavior indicative of a changing condition, as stated in instant claims 1, 16, 32, and 75-77. Rine et al. disclose performing comparisons to generate correlates and qualitative and/or quantitative deduction analyses (col. 5, lines 56-63 and Figure 5) which represent producing a comparison of two or more data integration maps and identifying correlative changes in at least two value sets, as stated in instant claims 1, 16, 32, and 75-77. Rine et al. disclose performing a compound treatment function by contacting each unit of the matrix with a test compound and a reference subtraction function wherein the appropriate reference response profile is subtracted from the response profile, and the difference stored in the knowledge base as the first chemical response profile (alternatively, the response profile is divided by the appropriate reference profile to yield an induction ratio) which is repeated for compounds or mixtures of compounds 2 through N (col. 11, fourth paragraph) as well as detecting changes and outputting correlative results and a user interface (Figures 6 and 7; col. 5, fourth and fifth paragraphs; col. 3, first paragraph; col. 7, last paragraph; col. 12, third paragraph), as stated in instant claims 1, 16, 32, and 75-77. Rine et al. disclose using an array

containing a different responder of a living thing in each unit which may comprise an organism's entire repertoire of responders including genes, gene regulatory elements, gene transcripts (mRNA) or translates (proteins), or a predetermined functional class or subset of the organism's entire repertoire as well as a sufficient ensemble of responders to deduce the action of a stimulus (col. 2, lines 30-44) which represent at least three different types of data elements within value sets (as stated in instant claims 1, 4, 16, 18, 19) and at least five components (as stated in instant claims 14, 29, and 41). Rine et al. disclose measuring gene expression levels in cells (col. 4, lines 11-17) and using various conditions/perturbations, including pharmaceutical agent stimuli, suspected pathogenic agents, and radiative energy (col. 3, lines 48-51) which represent a nucleic acid expression data element type and a physical interaction data element, as stated in instant claims 5, 13, 15, 20, 28, 31, 32, 40, 43, and 75-77. Rine et al. disclose measuring responses for each cell in the matrix under a variety of conditions, such as pH, temperature, medium, and osmolarity (col. 11, lines 21-28) which represents multiple data elements. Rine et al. disclose measuring cells of the matrix before and after interactions with a pharmacological agent which might include monitoring as a function of other variables such as stimulus intensity, duration, or time (col. 4, lines 51-57) which represents repeated measurements on at least two value sets with three data element types with perturbed conditions for substantially all components within at least one network (as stated in instant claims 8, 23, and 37) as well as obtaining a first integration map and producing a second integration map under a perturbed condition, as stated in instant claims 16, 32, 76, and 77. Values taken during the drug interaction measurements over time as discussed above in a 96-well microtiter plate represent value sets within the same network (measurements in the same well) as well as within different networks (measurements in different

wells) as stated in claims 9, 10, 24, and 25. Rine et al. disclose a system for creating physical matrices, storing the matrices in a database, and a comparison function (col. 3, lines 9-19) as well as repeating the process of creating response profiles for compounds 2 through N (any number, i.e. 3) (col. 11, lines 30-40) which represents data integration maps comprising changes in three or more value sets, as stated in instant claims 11, 26, and 38. Rine et al. disclose similarities in a shared response pathway in sterol biosynthesis between human cells and yeast cells resulting increased expression levels but in different nucleic acids when exposed to drug Mevacor (col. 6, lines 14-28). Rine et al. disclose using a microtiter plate to test an inhibitor on various strains of yeast which varies in no expression, increased expression, or decreased expression depending on the strains (col. 6, lines 44-54) which represents inversely coordinated changes in nucleic acid expression data elements, as stated in claims 12, 27, and 39. Rine et al. disclose measuring cells of the matrix before and after interactions (col. 4, lines 51-57) as well as constructing a stimulated physical matrix, detecting physical signals, storing the data, and iteratively storing signal matrix data for a plurality of stimuli to form a matrix database (col. 2, lines 4-15) which represents repeating steps at least once under a different perturbed condition, as stated in instant claims 30 and 42. Rine et al. disclose comparing a response profile to a reference profile and repeating the process for compounds or mixtures of compounds 2 through N (col. 11, lines 29-40). Rine et al. disclose using this procedure in testing drug administration (perturbation and physical interaction) to identify compounds with a particular biological effect (col. 1, lines 40-57). Rine et al. disclose steps to generate various response profiles (including value sets) for known and unknown stimuli (col. 2, lines 60-64). Rine et al. disclose using a wide variety of

stimuli and adjusting incubation conditions to preclude cellular stress (col. 3, lines 59-63). Thus, Rine et al. anticipate the instant invention.

Applicant summarizes the rejection and argues that Rine et al. compare values obtained from the same type of responders. This statement is found unpersuasive as the Rine provides ample evidence of comparing values from different types of data elements. It is reiterated that Rine et al. address this limitation several times, as noted below:

Rine et al. disclose constructing a **stimulated physical matrix (data integration map),** detecting a signal (value) at each unit and storing X and Y coordinates of a corresponding **(second) physical matrix and stimulus** (col. 2, lines 4-15) wherein two cells involved in each microarray qualify as two networks (col. 10, lines 38-41). Rine et al. also disclose comparing an output signal matrix to a matrix database (for correlating stimuli and responses (abstract and col. 1, line 66 to col. 2, line 3 and col. 2, lines 25-29) and performing comparisons to generate correlates and qualitative and/or quantitative deduction analyses (col. 5, lines 56-63 and Figure 5) which represents producing a comparison of two or more data integration maps and identifying correlative changes in at least two value sets. Furthermore, Rine et al. disclose using an array containing a different responder of a living thing in each unit which may comprise an organism's entire repertoire of responders including genes, gene regulatory elements, gene transcripts (mRNA) or translates (proteins), or a predetermined functional class or subset of the organism's entire repertoire as well as a sufficient ensemble of responders to deduce the action of a stimulus (col. 2, lines 30-44) which represent at least three different types of data elements within value sets. In addition, Rine et al. disclose measuring gene expression levels in cells (col. 4, lines 11-17) and using various conditions/perturbations, including pharmaceutical agent stimuli, suspected pathogenic agents, and radiative energy (col. 3, lines 48-51) which represent a nucleic acid expression data element type and a physical interaction data element. Rine et al. disclose measuring responses for each cell in the matrix under a variety of conditions, such as pH, temperature, medium, and osmolarity (col. 11, lines 21-28) which represents multiple data elements.

For example, measuring responses under a variety of conditions and then comparing them to a matrix database reasonably represents comparing values from different types of data elements.

Applicant argues that the latest claim amendments are not in Rine et al. This statement is found unpersuasive as the limitations are disclosed, as discussed in the rejection above. Applicant again argues that Rine et al. only disclose a single type of responder which has already been found unpersuasive above. Applicant again argues that Rine et al. are silent as to any comparison between the output signal matrices generated from different type of responders. Again, this is found unpersuasive as the different data element types in Rine et al. are discussed above. Applicant argues that Rine et al. fail to describe that the value sets are integrated and their correlative changes are identified relative to one or more of the value sets. This statement is found unpersuasive as Rine et al. disclose comparing an output signal matrix to an output signal matrix database (containing other matrices) for correlating candidate stimuli and responses (abstract and col. 1, line 66 to col. 2, line 3 and col. 2, lines 25-29) which represents identifying correlative changes relative to one or more of the value sets between two or more data integration maps. Applicant's arguments are deemed unpersuasive for the reasons given above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-33, 35-43, and 75-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Thalhammer-Reyero (US 2005/0273305 A1). This rejection is maintained for claims 1-2, 4-33, 35-43 and necessitated by amendment for claims 75-77.

Thalhammer-Reyero discloses methods for modeling and simulation of biochemical networks of pathways, including metabolic, signal transduction and regulatory pathways within a cell or across cells, determining the effect that modulating one or more reactions in a biochemical pathway has on an operation of the biochemical pathway, and for simulating or predicting an altered physiological state of cells (abstract) as stated in the preamble of instant claims 1, 16, 32, and 75-77. Thalhammer-Reyero discloses a method of predicting a behavior of a biochemical system, comprising obtaining a first integration map of a biochemical system comprising value sets of two or more data elements for at least one network, producing a second data integration map of said biochemical system under a perturbed condition, said second data integration map comprising perturbed value sets of two or more data elements for said at least one network, comparing and identifying correlative changes in at least two value sets relative to one or more value sets in the data integration map with said perturbed condition, wherein said correlative changes predict a behavior of said biochemical system as well as an integrated framework and an integration of a variety of forms of knowledge representation (0003, 0006, 0014-0017, 0020, 0093, 0453, claims 259 and 142) as stated in instant claims 1, 9, 10, 16, 32, 24, 25, and 75-77. Thalhammer-Reyero discloses modeling disease specific conditions and comparing against each other or specifed values (0028, 0084), as stated in instant claims Thalhammer-Reyero discloses providing output (0036, 0097, 0140). Thalhammer-Reyero discloses a biochemical system is selected from the group consisting of a cell, tissue and

organism, or a constituent system thereof (claim 260), as stated in instant claims 2, 17, and 33. Thalhammer-Reyero discloses three or more data elements (claim 413), as stated in instant claims 4, 11, 18, 19, 26, and 38. Thalhammer-Reyero discloses data elements corresponding to physical interactions (0017), as stated in instant claims 5, 20. Thalhammer-Reyero discloses three or more networks (claim 412), as stated in instant claims 6, 21, and 35. Thalhammer-Reyero discloses two or more perturbed conditions (claim 261), as stated in instant claims 7, 8, 22, 23, 36, and 37. Thalhammer-Reyero discloses inverse changes (0434, 0514), as stated in instant claims 12, 27, and 39. Thalhammer-Reyero discloses correlative changes in at least two value sets within said second data integration map further comprise value sets selected from the group consisting of protein expression, polypeptide-polypeptide interaction, nucleic acid-polypeptide interaction, metabolite abundance, and growth rate (claim 414), as stated in instant claims 13, 28, and 40. Figure 2 shows at least five components, as stated in instant claims 14, 29, and 41. Thalhammer-Reyero discloses allowing repeated use of entities as building blocks in a variety of situations (0094, 0141, 0576), as stated in instant claims 30 and 42 Thalhammer-Reyero discloses behavior is selected from the group consisting of cellular phenotype, biochemical activity, expression level and accumulation level (claim 262), as stated in instant claims 15, 31, and 43.

Thus, Thalhammer-Reyero anticipates the instant invention.

Applicant argues that the Thalhammer-Reyero claims and abstract were added in a preliminary amendment. While this may be the case, the originally filed 180 page specification provides adequate written support for these claims and abstract. Applicant summarizes the

rejection. Applicant argues that Thalhammer-Reyero cannot anticipate the dependent claims since the independent claims are not supported. This statement is found unpersuasive as the independent claims have written support in the originally filed specification of Thalhammer-Reyero.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

January 9, 2008

/Carolyn Smith/
Primary Examiner
AU 1631